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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/943,347	08/31/2001	Hideya Takeo	Q65986	8688

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EXAMINER	
LAVIN, CHRISTOPHER L	
ART UNIT	**PAPER NUMBER**
2621	

DATE MAILED: 06/28/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/943,347	TAKEO, HIDEYA	
	Examiner	Art Unit	
	Christopher L. Lavin	2621	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on *08 March 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,6,8,9 and 11-16* is/are rejected.

7)☒ Claim(s) *4,7 and 10* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *08 March 2005* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☒ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Claim Objections

1. The following quotations of 37 CFR § 1.75(a) is the basis of objection

(a) The specification must conclude with a claim particularly pointing out and distinctly claming the subject matter which the applicant regards as his invention or discovery.

Claims 12 – 14 are objected to under 37 CFR § 1.75(a) as failing to particularly point out and distinctly claim the subject matter which the applicant regards as his invention or discovery. All three claims refer to "feature values", which is not mentioned in claim 1. Rather "feature values" is mentioned in claim 3. For the purposes of this action the examiner assumed the applicant intended for these three claims to depend from claim 3.

Claim Rejections - 35 USC § 102

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

3. Claims 1 – 3, 6, 9 are rejected under 35 U.S.C. 102(b) as being anticipated by Clarke (5,799,100).

4. In regards to claim 1, Clarke discloses the system of claim 1 in Fig. 1 with further detail elaborated upon throughout this rejection. The paragraph starting at column 4, line 27 discloses a system for image enhancement and analysis of abnormal regions. Portion 5 of Fig. 1 discloses the step of classifying an image region as either normal tissue or an abnormal shadow. Portion 7 of Fig. 1 discloses a computer monitor display

used to output information on the prospective abnormal shadows detected by the system. Portion 6 of Fig. 1 discloses the step of classifying an abnormal shadow as either benign or malignant. The paragraph starting at column 5, line 12 discloses that segmented images are output to the monitor system that displays the abnormal shadow region. Inherent with outputting regions of interest and determining whether a shadow is malignant or benign is providing some means to alert the user through the display system what kind of mass has been discovered.

5. In regards to claim 2, Clarke discloses in portion 6 of Fig. 1 the step of computing the probability that an abnormal shadow is malignant. This is further discussed in the paragraph staring on column 16, line 9. The probability acts as an index of malignancy. The only reason to compute such information would be to share it with the user through the display system.

6. In regards to claims 3, 6, and 9, Clarke discloses portion 5 of Fig. 1 the step of classifying tissue as either mass or normal, this creates a normalcy function. In portion 6 of Fig. 1 and further described in the paragraph starting at column 16, line 9, Clarke discloses malignancy and benignancy functions for classifying a mass.

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 1, 3, 15, 16 are rejected under 35 U.S.C. 102(b) as being anticipated by Brzakovic ("An Approach to Automated Detection of Tumors in Mammograms", IEEE Transactions on Medical Imaging. Vol. 9, No. 3, September 1990).

In regards to claim 1, A prospective abnormal shadow detecting system comprising a prospective abnormal shadow detecting means which detects a prospective abnormal shadow in an image on the basis of image data representing the image and a prospective abnormal shadow information output means which outputs information on the prospective abnormal shadow detected by the prospective abnormal shadow detecting means, wherein the improvement comprises that a malignancy judging means which judges whether the prospective abnormal shadow detected by the prospective abnormal shadow detecting means is malignant or benignant is provided (Section: IV. Tumor Classification), and the prospective abnormal shadow information output means outputs the information on the prospective abnormal shadow in such a manner that whether the prospective abnormal shadow is malignant or benignant as judged by the malignancy judging means can be distinguished (Section: IV. Tumor Classification; Figure 9).

In regards to claim 3, A prospective abnormal shadow detecting system as defined in claim 1 in which the malignancy judging means judges whether the prospective abnormal shadow detected by the prospective abnormal shadow detecting means is malignant or benignant by obtaining a benignancy evaluation function value which is a value of an evaluation function for benignancy, a malignancy evaluation function value which is a value of an evaluation function for malignancy, and a normalcy

evaluation function value which is a value of an evaluation function for normalcy by defining feature values of the image data by a predetermined function (Sections A. Measurements and B. Classification Rules: Evaluation functions are found for each of the four steps for the different levels. Feature values include the calculated measurements for each of the four levels, for example area.), and comparing the normalcy evaluation function value with the benignancy evaluation function value and the normalcy evaluation function value with the malignancy evaluation function value (Sections A. Measurements and B. Classification Rules).

In regards to claim 15, A prospective abnormal shadow detecting system as defined in claim 1, wherein whether the prospective abnormal shadow is malignant or benignant as judged by the malignancy judging means is distinguished visually (Figure 9: The Tumors are visually identified in figure 9.).

In regards to claim 16, A prospective abnormal shadow detecting system as defined in claim 1, wherein the information on the prospective abnormal shadow output by the prospective abnormal shadow information output means comprises a visible marking (Figure 9: The Tumors are visually identified in figure 9 using text.).

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

10. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

11. Claims 5, 8, and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Clarke in view of Abdel-Motaleb (5,768,333).

12. In regards to claims 5, 8, and 11, Clarke as shown above, in response to claim 3, has everything in common with claims 5, 8, and 11 except for explicitly stating that Mahlanobis distance is used with the normalcy, benignancy, and malignancy functions.

13. Abdel-Motaleb teaches of a system for classifying abnormal shadows. Abdel-Motaleb discloses in the paragraph starting at column 8, line 60 using Mahalanobis distance to compute the benignancy and malignancy functions.

14. Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to use Mahalanobis distance (as taught by Abdel-Motaleb) when analyzing abnormal shadows. When dealing with a decision making system that outputs functions suggesting the likelihood of malignancy or benignancy the system needs the third options of normalcy. In order to provide consistant results all three functions should be based upon the same design, in this case Mahalanobis distance. Mahalanobis distance is a very effective way of finding the similarity between sets of values. The system disclosed by Clarke uses Neural Networks for classification,

similarity is one of the foundations Neural Networks are based upon. Thus using Mahalanobis distance can provide more accurate results, preventing many unnecessary surgeries and catching cancer at its very earliest stages.

15. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Brzakovic in view of Nakajima (5,784,482).

In regards to claim 12, Brzakovic discloses a system for detecting and classifying abnormal shadows as shown in the rejection of claim 3. Brzakovic discloses in the first paragraph of section IV. Tumor Classification that for a more accurate classification additional measurements should be taken. In other words, Brzakovic suggests that in order to get a more accurate result more levels should be added to the classification hierarchy (figure 3). Brzakovic does not disclose using an iris filter as an additional measurement.

Nakajima teaches (col. 12, lines 1 – 12; figure 1) that an iris filter can be used to identify a tumor.

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to include an iris filter output (as taught by Nakajima) as a measurement in the classification hierarchy disclosed by Brzakovic. As previously stated Brzakovic states that to get a more accurate classification more measurements need to be taken. Nakajima has shown that an iris filter is an accurate way of identifying tumors. Thus using an iris filter will further increase the accuracy of Brzakovic's system.

16. Claims 13 and 14 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brzakovic in view of Smith (6,631,204).

In regards to claims 13 and 14, Brzakovic discloses in section B. Classification Rules that margins are calculated based on thresholds in order to classify the structures. Brzakovic only shows displaying the final result (figure 9), but does not disclose outputting other measurement values. However, outputting intermediary computations along with the final result is well known in the art as shown by Smith (col. 4, lines 18 – 40).

Therefore it would have been obvious to one having ordinary skill in the art at the time of the invention to display the margin and feature values along with the outputted result (processed image area and classification) as taught by Smith in the system disclosed by Brzakovic. A doctor can not simply take the word of a machine, by displaying the feature and margin values the system can allow the doctor to come to his or her own conclusion based on the data. Thus making the doctor's decision easier.

Allowable Subject Matter

17. Claims 4, 7, and 10 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

18. The following is a statement of reasons for the indication of allowable subject matter: The art of record does not teach nor does it suggest the specific features called for in the claims, particularly computing two likelihood ratios based on normalcy,

malignancy and benignancy functions and using these ratios to determine whether a tumor is benign or malignant.

Response to Arguments

19. Applicant's arguments filed 03/08/05 have been fully considered but they are not persuasive.

20. The applicant argues that Clarke does not show a result as Malignant or Benignant. As shown in the rejection Clarke inherently discloses this step, or the system disclosed by Clarke would be useless.

21. The applicant argues that Clarke does not disclose a normalcy function. As the function in the claim argued is not clearly define the examiner is free to broadly interpret the term, and thus as shown in the rejection Clarke does disclose a normalcy function. A value of some sort would be required in the classification. How else can the system decide between two options?

22. Please note that new rejections for claims 1 and 3 are provided in order to deal with the new claims 12 – 16.

Conclusion

23. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the

shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher L. Lavin whose telephone number is 571-272-7392. The examiner can normally be reached on M - F (8:30 - 5:00).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Mancuso Joseph can be reached on (571) 272-7695. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

CLL

BRIAN WERNER
PRIMARY EXAMINER